

Application Number 10/813,307  
Amendment dated November 16, 2006  
Responsive to Office Action mailed June 16, 2006

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REMARKS

This amendment is responsive to the Office Action dated June 16, 2006. Applicant has amended claims 1, 18-23 and 29. Claims 1-5, 17-32 and 41-47 are pending.

Drawing Objections

In the Office Action, the Examiner objected to the drawings under 37 CFR 1.83(a) for failing to show every feature of the invention specified in the claims. Applicant disagrees with the objection of the Examiner. The elements cited by the Examiner are listed below with the corresponding numeral. These include:

The power source (34) includes an inductive coupling circuit (39) to generate power from an inductive element external to the body lumen;

a telemetry circuit (32) to receive the control signal as a telemetry signal from an external controller (24);

an inductive coupling circuit (39) to sense the presence of an external inductive element as the control signal;

an inductive coupling circuit (39) to generate power from an inductive element external to the body lumen and thereby drive the detachment mechanism with the generated power;

a sensor (30), mounted to the device (20) housing, to sense at least one condition within the body lumen;

an electrical pulse generator (31), mounted within the device (20) housing, to generate an electrical stimulation waveform; and

one or more electrodes electrically coupled to the electrical pulse generator (31) and mounted to the device (20) housing to deliver the electrical stimulation waveform to the body lumen.

Applicant requests that the Examiner withdraws the objection to the drawings.

Claim Objections

In the Office Action, the Examiner objected to the following claims because claim 18 recites the limitation "the power source" in line 1 and claim 19 recites the limitation "the power source" in line 1 without proper antecedent basis. Applicant has amended claims 18 and 19 to

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correctly depend from claim 17, in which a power source is recited. Applicant requests that the Examiner withdraws the objections to claims 18 and 19 in view of the current amendments.

### Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 17-18, 25, 28-29, 41, 43, 45-47 under 35 U.S.C. 102(b) as being anticipated by Silverstein et al. (US 5,247,938). The Examiner also rejected claims 1-3, 18-19, 24-27, 29-31, 45-46 under 35 U.S.C. 102(e) as being anticipated by Kilcoyne et al. (US 6,689,056). The Examiner also rejected claims 1-6 and 29-32 under 35 U.S.C. 102(b) as being anticipated by Banko (US 3,844,272). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Each of the references of Silverstein, Kilcoyne, and Banko fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b) and 35 U.S.C. 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Independent claim 1 requires a device housing sized for introduction into and residence completely within the body lumen, a fixation mechanism to attach the device housing to a surface within the body lumen, and a controlled detachment mechanism to selectively detach the device housing from the surface of the body lumen. Independent claim 29 also requires similar elements. Each reference of Silverstein, Kilcoyne, and Banko fails to duplicate the required elements of independent claims 1 and 29.

With regard to Silverstein, the Examiner indicated that Silverstein discloses the elements of the claimed invention. The Examiner characterized the medical device as probe 40, the fixation mechanism as "suction chamber 50 which gently attaches to the mucosa,"<sup>1</sup> and the detachment mechanism as using service loop 72, vacuum lumen 52, and probe head 40 "in which suction is used for maintaining the probe on the intestinal wall."<sup>2</sup> However, the Silverstein device fails to disclose two elements required in the independent claims.

First, the Silverstein device is not sized for residence completely within the body lumen. Silverstein teaches that "service loop 72 is made sufficiently long that it can remain attached to the suction source until the tip of the endoscope 92 clears the mouth, the anus, or other opening

<sup>1</sup> Silverstein et al., Col. 4, ll. 40-43.

<sup>2</sup> Silverstein et al., Col. 6, ll. 1-2.

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of the digestive tract.”<sup>3</sup> In addition, Silverstein discloses that “The service loop 72, coupled to the probe 40 or a plurality of probes 40, arranged either in series or parallel, is brought out of the surgical opening”<sup>4</sup> in some embodiments. In other words, the Silverstein device requires service loop 72 to exit the patient at all times. Therefore, the Silverstein device is not sized for residence completely within the body lumen.

Second, the Silverstein device fails to include a controlled detachment mechanism of the medical device. Silverstein suggests several methods for attaching probe 40, such as “a temporary glue,” “suction chamber 50,” and “a depressible membrane 49.” However, nowhere does Silverstein suggest a controlled detachment mechanism of probe 40 that is capable of removing the attached probe 40. Silverstein discusses removing probe 40 when “the suction is disengaged”<sup>5</sup> through service loop 72, “air pressure [is] applied through the suction lumen,”<sup>6</sup> the substance is “biodegradable and automatically release[s] the probes after a period of time,”<sup>7</sup> or “it may be necessary to surgically remove the suture and remove the probe.”<sup>8</sup> Biodegradable materials cannot be controlled once in the patient, as they are subject to the surrounding environment. None of these methods for removing probe 40 anticipate a controlled detachment mechanism within the device housing, as required by independent claims 1 and 29.

With regard to Kilcoyne, the Examiner indicated that Kilcoyne disclosed the elements of the claimed invention. Applicant interprets the Examiner’s characterization of the device housing as monitor 18, the fixation mechanism as deployment catheter 138, attachment cavity 124, and tissue pin 164, and the detachment mechanism as “materials in [an alligator] clip dissolve...the clip will break free of the esophagus 30.”<sup>9</sup> Applicant believes that the Examiner is inadvertently combining multiple embodiments disclosed by Kilcoyne. Nonetheless, Applicant disagrees with the Examiner because none of the Kilcoyne devices teach or suggest the elements of independent claims 1 and 29.

<sup>3</sup> Silverstein et al., Col. 6, ll. 2-6.

<sup>4</sup> Silverstein et al., Col. 7, ll. 15-18.

<sup>5</sup> Silverstein et al., Col. 12, l. 38.

<sup>6</sup> Silverstein et al., Col. 12, ll. 40-41.

<sup>7</sup> Silverstein et al., Col. 12, ll. 47-48.

<sup>8</sup> Silverstein et al., Col. 12, ll. 51-52.

<sup>9</sup> Kilcoyne et al., Col. 9-10, ll. 66-2.

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Kilcoyne fails to teach or suggest a controlled detachment mechanism. Kilcoyne states a clip "can hold the monitor in place by capturing, or "pinching," the mucosa and submucosa of the esophagus 30 between its arms or "jaws."<sup>10</sup> The detachment of the clip is described "As materials in the clip dissolve, the tension in the clip that causes it to hold onto, or pinch, the esophagus 30 will eventually decrease, and the clip will break free of the esophagus 30."<sup>11</sup> The dissolvable materials in the clip are subject to the environment, and any changes that may occur. The Kilcoyne device detachment mechanism is at the mercy of the surrounding environment in order to detach from esophagus 30. In this manner, the clip disclosed by Kilcoyne cannot be a controlled detachment mechanism, as required by claims 1 and 29.

With regard to Banko, the Examiner indicated that Banko teaches the elements of the claimed invention. Applicant interprets from the Office Action that the Examiner characterized the Banko device as including a device housing 10, the fixation mechanism as suction from "conduit 14 which aids in drawing the tissue to be sampled into the cup 48,"<sup>12</sup> and the detachment mechanism as cutting edge 49 and cutting edge 59 that "cuts off the tissue sample as the member is rotated."<sup>13</sup> Applicant does not agree with the Examiner's characterization of the Banko device. The Banko device is a "Surgical instrument for taking tissue samples."<sup>14</sup> Taking tissue samples through the process of cutting off tissue does not constitute a fixation mechanism and detachment mechanism. The Banko device is never fixed to the tissue while taking the tissue sample. Banko fails to disclose the claimed invention.

In addition, the Banko device is not sized for residence completely within the body lumen. The Banko device includes instrument 10. Banko discloses that instrument 10 includes a first tubular member 12 which extends substantially the entire length of the instrument."<sup>15</sup> Banko also states that "The operator rotates the first tubular member 12 by turning the knob 40 [of instrument 10]."<sup>16</sup> In order for the operator to turn knob 40, knob 40 resides outside of the

<sup>10</sup> Kilcoyne et al., Col. 9, ll. 58-61.

<sup>11</sup> Kilcoyne et al., Col. 9-10, ll. 66-2.

<sup>12</sup> Banko, Col. 4, ll. 53-55.

<sup>13</sup> Banko, Col. 4, l. 64.

<sup>14</sup> Banko, Abstract.

<sup>15</sup> Banko, Col. 3, ll. 21-23.

<sup>16</sup> Banko, Col. 4, ll. 59-61.

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body lumen along with at least a portion of instrument 10. Therefore, it is unclear to Applicant how the Banko device is sized for residence completely within the body lumen.

Dependent claims 2-5, 16-27, 29-32 and 41-47 are allowable for at least the reasons put forth above with regard to independent claims 1 and 29.

Silverstein, Kilcoyne and Banko all fail to disclose each and every limitation set forth in claims 1-5, 16-32 and 41-47. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-5, 16-32 and 41-47 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

#### Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 21-23, 42 and 44 under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. The Examiner also rejected claims 21 and 42 under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. in view of Christopherson et al. (US 6,021,352). The Examiner also rejected claims 22 and 44 under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. in view of Cimochowski et al. (US 5,967,986). The Examiner also rejected claim 23 under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al. in view of Imran et al. (US 6,535,764).

Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 21-23, 42 and 44 are dependent upon independent claims 1 and 29. As described above, independent claims 1 and 29 are allowable over all of the references of Silverstein, Kilcoyne and Banko. Therefore, claims 21-23, 42 and 44 are allowable for at least the reasons with regard to independent claims 1 and 29.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 21-23, 42 and 44 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

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**Rejection for Obviousness-type Double Patenting:**

The Examiner provisionally rejected claims 1-3, 16, 18-19, 24-27, 29-31, 45-46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,689,056.

The Examiner also provisionally rejected claims 1, 18, 24-27, 29, 45-46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-17, 62-87 of copending Application No. 10/833,776

The Examiner also provisionally rejected claims 1-3, 18, 24-27, 2-31, 45, 46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13-16-55-58, 61-66 of copending Application No. 10/687,296

The Examiner also provisionally rejected claims 1-3, 18, 19, 24-27, 29-31, 45, 46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-58, 66, 69, 71, 73 of copending Application No. 10/896,533

The Examiner also provisionally rejected claims 1-3, 18, 24-31, 45, 46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/835,425

Applicants note the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied.

**CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any

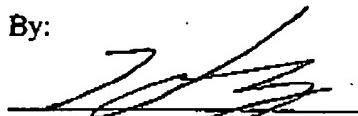
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additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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November 16, 2006  
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